REMARKS

Claims 1 and 6 are amended. Claims 12 and 24-31 are cancelled. Claims 1-10 and 18-22 are pending in the application.

Applicant acknowledges the Examiner's withdrawal of claims 24-31 as being directed toward a non-elected invention. Claims 24-31 are appropriately cancelled.

Claims 1-10, 12 and 18-22 stand rejected under 35 U.S.C § 112, first paragraph as failing to comply with the written description requirement and lack of enablement. An Examiner interview was conducted on October 21, 2004 to address these issues, with follow-up discussions occurring on October 25 and 26. During the examiner interview, the language of the claims was discussed. The claim amendments presented in this Response were indicated as overcoming the rejections so long as public availability of the recited coding sequence (as recited in amended claims 1 and 6) could be established. It was also agreed to cancel claim 12. Applicant provides evidence as to the public availability of the recited sequence as follows.

A recombinant clone containing the recited full length factor VIII nucleotide sequence is on deposit and is available from the American Type Culture Collection (Manassas, VA) under ATCC accession number 39,812. A copy of the relevant page of the ATCC website is enclosed herewith indicating the availability, price and ordering information for obtaining the pSP64-VIII plasmid containing the full length human factor VIII sequence. As indicated, the depositor is Genetics Institute, Inc. (Cambridge, MA) . A complete description of how the nucleotide sequence encoding full length factor VIII was isolated is described in U.S. Patent No. 4,757,006. The sufficiency of the isolation description, and the availability of the clone is corroborated by Genetics Institute, Inc.'s reliance upon the 4,757,006 disclosure and the ATCC as set forth by the depositor in their

U.S. Patent Nos. 4,868,112; 4,904,584; 4912,040; 5,004,803; 5,189,349; 5,250,421; 5,422,260; 5,451,521; and 5,563,045. The molecular cloning of the cDNA is also described by Toole, J.J. et al (molecular Cloning of a cDNA Encoding Human Antihaemophilic Factor, Nature 312: 342-347, 1984) which is referenced both by the ATCC site (enclosed) and by applicant's specification. Accordingly, the public has access to both the clone and the methodology for isolation of the human fetal liver factor VIII nucleotide sequence.

The public availability of the recited Factor VIII nucleotide sequence is further evidenced by the use of the pSP64-VIII plasmid (ATCC accession number 39,812) by other than the original depositors. This use and availability is apparent upon review of the following list of patents, each of which indicates the ATCC 39,812 as source of the factor VIII sequence: 5,814,482; 5,789,245; 5,843,723; 6,015,686; 6,015,694; 6,156,497; 6,342,372; and 6,376,236. Accordingly, the public availability of ATCC 39,812 and the knowledge of how to obtain the full length factor VIII nucleotide sequence without undue experimentation, either from pSP64-VIII or native sources, is sufficient to meet the requirements of 37 CFR § 1.802. Independent claims 1 and 6, and corresponding dependent claims 2-5, 7-10 and 18-22 are therefore fully enabled and meet the written description requirement.

For the reasons discussed above, pending claims 1-10 and 18-22 are allowable. Applicant requests formal allowance of the pending claims in the Examiner's next action.

Respectfully submitted,

Dated: October 26, 2004 By: Jennifer J. Taylor

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Attachment: 2 pages